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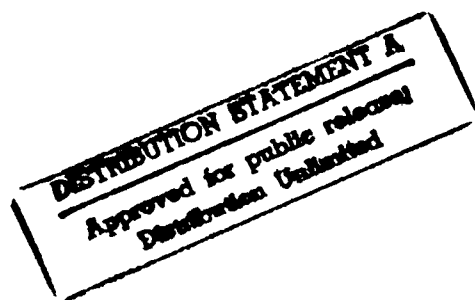
The Prevalence of Artificial Lens Implants in the Civil Airman Population

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16. Abstract <p>The use of artificial lens implants to correct for aphakia has become increasingly prevalent in the United States. This study analyzes the distribution of intraocular lens (IOL) implants in the civil airman population by type (unilateral, bilateral), class of medical certificate, and gender for a 4-year period (1982-85). Medical records were evaluated for all certified airmen who were carrying pathology codes for aphakia and artificial lens implant during the study period. The percentage increase in the prevalence of airmen with artificial lenses was higher for bilateral, second-class medical certificate holders, and female aphakics. However, the incidence of total and unilateral artificial lens implants declined in 1985. The implications of the study's findings for aeromedical certification are discussed. A change in the methods used to evaluate trends in the use of IOL in the airman population is recommended.</p>			
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THE PREVALENCE OF ARTIFICIAL LENS IMPLANTS IN THE CIVIL AIRMAN POPULATION

INTRODUCTION

Cataract, a condition in which there is a loss of transparency of the crystalline lens or its capsule, is the third leading cause of blindness in the United States (1). Normally associated with aging, cataracts account for 1 out of every 7 cases of blindness among persons 45 years of age or older (2). In the United States, cataract surgery accounts for about 40% of all eye operations (3), with a contemporary surgical success rate of over 98% (4).

Aphakia, a condition in which the crystalline lens of the eye has been extracted, and artificial or intraocular lens (IOL) implants to correct aphakia, sometimes referred to as "pseudophakia," have been associated with increased risk while piloting an aircraft. Dille & Booze (5), in a 1979 study of accidents involving airmen with vision pathologies, found that aphakia and artificial lens implant populations had significantly higher accident rates when compared to the total airman population. In a follow-up study of 1980-81 airman accidents, Dille and Booze (6) found that pilots with aphakia and artificial lens implant, when compared to the total airman population, had higher accident rates in two categories of exposure: accident rates per 1,000 airmen per year and accident rates per 100,000 hours of recent flight time. Furthermore, a study of aphakia in the civil airman population from 1982-85 found an increasing prevalence of airmen with cataract surgery (7).

The implantation of an IOL has become the standard therapeutic modality for the correction of aphakia, and is the primary reason for the increased popularity of early surgical intervention in the medical management of cataracts. In 1980 approximately 396,000 cataract procedures were performed in the United States of which 30% of these operations included the implantation of an IOL (8); in 1984 approximately 779,000 cataract procedures

were performed and 84% included the implantation of an IOL (3,9); in 1988 nearly one million cataract operations were performed, over 90% of which included the implantation of an IOL (1); and in 1990 approximately 1.385 million cataract operations were performed and 98% of these operations included the implantation of an IOL (10). Advantages of an intraocular lens over other forms of post-surgical vision correction include: freedom from patient handling of lenses; normal peripheral vision; minimum aniseikonia and rapid return to binocular vision (3); and minimum image size magnification (1.5 to 2%) (11).

An applicant may apply for 1 of 3 classes of airman medical certificate: first-class (airline transport pilot); second-class (commercial pilot); and third-class (private pilot). The Federal Aviation Administration (FAA) has different medical standards for each class of certificate (12). The designated Aviation Medical Examiner may issue a medical certificate to an applicant with aphakia or IOL for a third-class medical certificate, if the applicant meets certain medical standards. Applicants with aphakia or IOL for first- and second-class airman medical certificates are deferred issuance of a certificate, and their applications are submitted to the FAA for further consideration. A waiver can be issued by the FAA for such applicants (12), after review of a complete ophthalmological evaluation.

The Federal Air Surgeon has requested research on vision disorders as they affect airman performance problems related to aging, surgical intervention, and other treatment. The Vision Research Section, Civil Aeromedical Institute, in collaboration with the Aeromedical Certification Division, performed an epidemiologic study on aphakia and artificial lens implant in civil airmen

and their association to aviation accident risk during the study period 1982-85. Due to the size of the database, a separate report on aphakia has already been completed and the report on aviation accident risk will be presented in a future publication. The increased use of IOL to correct aphakia; the different types of lenses; and the numerous technological changes in materials, styles and applications, warrants a separate discussion of how these lenses may affect aviation safety and airman performance. This paper presents a descriptive analysis of artificial lens implants in the civil airman population during the study period.

METHODS

The study protocol included:

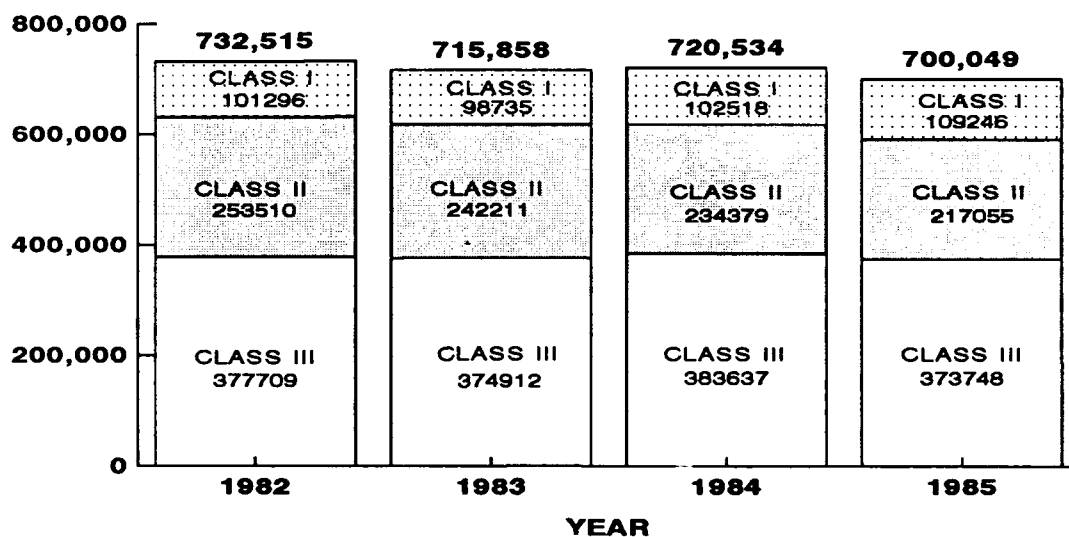
1. A listing was generated from FAA computer files identifying all civil airmen who were issued airman medical certificates between January 1, 1980, and December 31, 1985, and carried one or both of the FAA-specific pathology codes 134 (aphakia) and 160 (artificial lens implant).
2. The medical records of these airmen were reviewed, with selected information extracted and recorded on individual data cards.
3. A Vision Defect Database was constructed from the individual data cards and FAA computer files; it contained all available demographic (name, date of birth, sex, restrictions, etc.) and medical (date and type of cataract extraction, date and type of artificial lens implanted, type of corrective modality, etc.) data on these aphakic airmen.
4. The frequency of active airmen (those holding a current medical certificate) with aphakia and IOL was determined as of December 31 of each year of the study period (Note: Aeromedical certification guidelines consider an airman to be active for a period of 24 months after the month in which the certificate is issued.).
5. Pseudophakic airmen were stratified by type (unilateral, bilateral) of IOL, effective class of medical certificate held (first-, second-, and third-class), gender, and age.
6. Point prevalence and incidence of airmen with IOL were calculated using the total active airman populations, extracted from the annual issues of the Aeromedical Certification Statistical Handbook (13), for each year of the study. Since the use of an IOL is dependent on the presence of aphakia, IOL prevalence was also calculated using the total aphakic airman population for each year of the study.

RESULTS

Between January 1, 1980, and December 31, 1985, 3,499 airmen, who were issued medical certificates, were identified with pathology codes 134 and/or 160. Upon review of the medical records, it was discovered that 156 airmen were inappropriately coded and 10 medical records were not retrievable, resulting in a total aphakic airman study population of 3,333, of which 1,828 had artificial lens implants.

The trends in the total active civil and aphakic airman populations during the study period by class of medical certificate and by year are presented in Figure 1, and the total active civil and aphakic airman populations by gender and by year are presented in Figure 2. While the total airman population has declined over the study period, decreasing by 4.43% since 1982, the total aphakic airman population has escalated, increasing by 25.78% during the same period. By class of medical certificate, first-class increased (7.85%), and second- (-14.38%) and third-class (-1.05%) decreased in frequency in the total airman population since 1982. By contrast within the total aphakic airman population, first- (28.18%), second- (31.13%) and third-class (24.02%) aphakic airman populations increased in frequency during this period. By gender, females (-5.13%) and males (-4.39%) decreased in frequency in the total airman population since 1982. However, during the same period, females (-2.50%) decreased while males (26.43%) increased in frequency in the aphakic airman population.

TOTAL ACTIVE CIVIL AIRMAN POPULATION BY CLASS AND YEAR



TOTAL ACTIVE APHAKIC CIVIL AIRMAN POPULATION BY CLASS AND YEAR

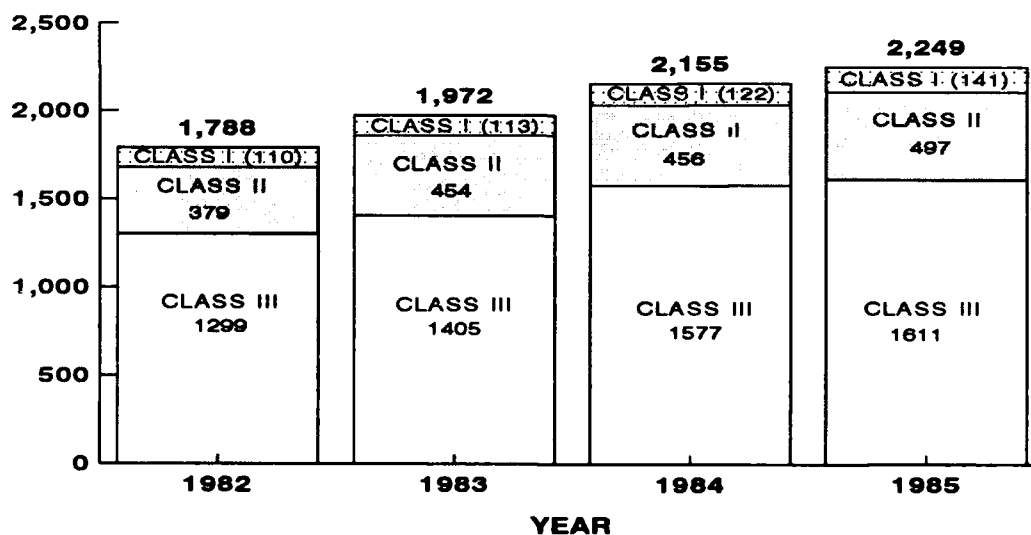
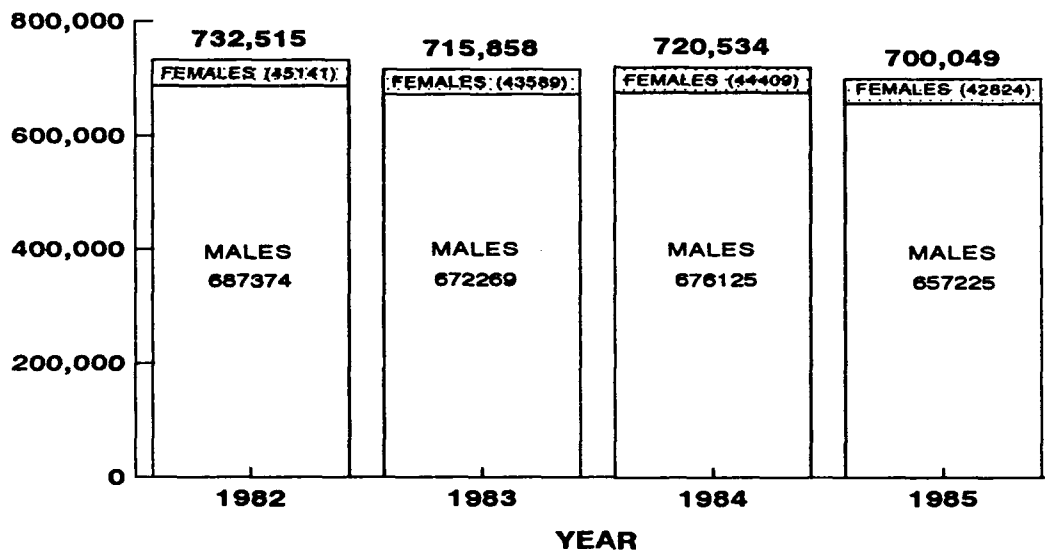


Figure 1

TOTAL ACTIVE CIVIL AIRMAN POPULATION BY GENDER AND YEAR



TOTAL ACTIVE APHAKIC CIVIL AIRMAN POPULATION BY GENDER AND YEAR

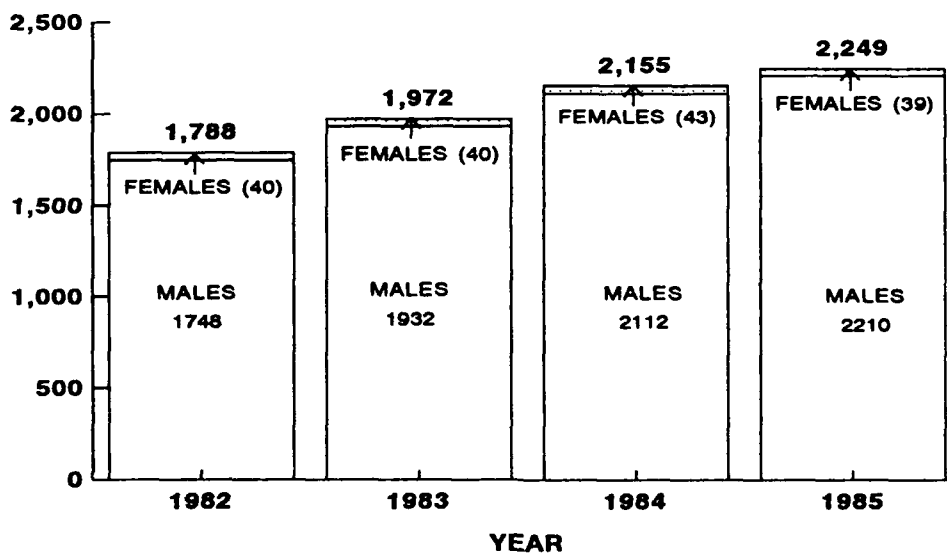


Figure 2

**FREQUENCY I.O.L. AIRMEN
BY TYPE AND YEAR**

YEAR	UNILATERAL	BILATERAL	TOTAL
1982	566	171	737
1983	709	273	982
1984	852	388	1240
1985	931	489	1420

**FREQUENCY I.O.L. AIRMEN
BY CLASS AND YEAR**

YEAR	CLASS I	CLASS II	CLASS III	TOTAL
1982	49	180	508	737
1983	60	242	680	982
1984	77	292	871	1240
1985	97	330	993	1420

**FREQUENCY I.O.L. AIRMEN
BY GENDER AND YEAR**

YEAR	FEMALE	MALE	TOTAL
1982	13	724	737
1983	19	863	982
1984	27	1213	1240
1985	26	1394	1420

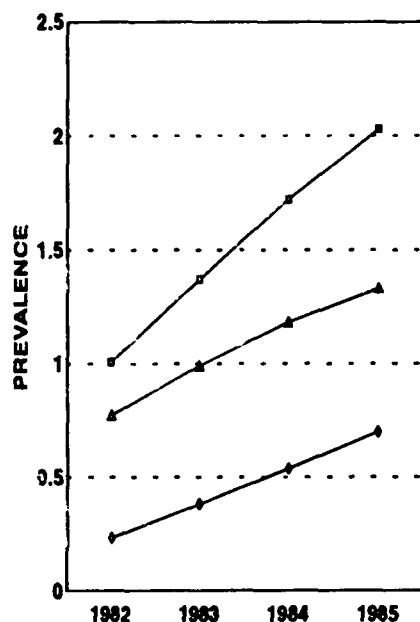
I.O.L. - INTRAOCULAR LENS

Table 1

The frequency of pseudophakic airmen (henceforth called "IOL airmen") by type of IOL, by class of medical certificate, and by gender and by year are presented in Table 1. By type of IOL, total (92.67%), unilateral (64.49%), and bilateral (185.96%) IOL airmen increased in frequency

between 1982 and 1985. By class of medical certificate held, first- (97.96%), second- (83.33%), and third-class (95.47%) IOL airmen increased in frequency during the same period. By gender, female (100.00%), and male (92.54%) IOL airmen increased in frequency since 1982.

**PREVALENCE OF I.O.L.
AIRMEN PER 1000 AIRMEN
BY TYPE AND YEAR**

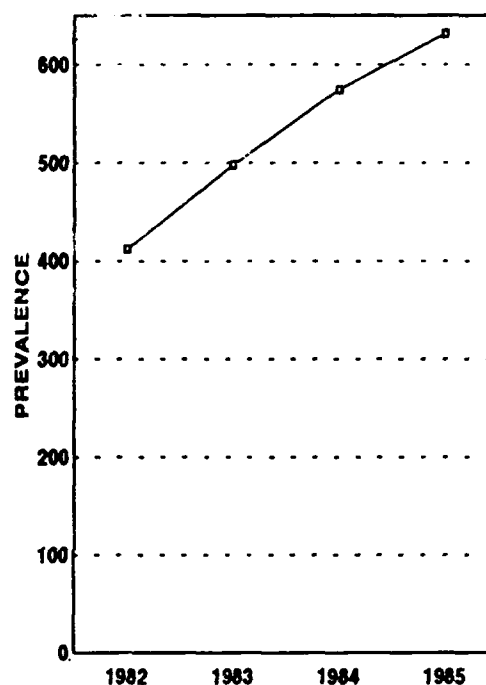


UNILATERAL	→	0.773	0.99	1.162	1.33
BILATERAL	→	0.233	0.361	0.538	0.699
TOTAL	→	1.006	1.372	1.721	2.028

YEAR

I.O.L. = INTRAOCULAR LENS

**PREVALENCE OF I.O.L.
AIRMEN PER 1000 APHAKIC
AIRMEN BY YEAR**



TOTAL	→	412.192	497.972	574.406	631.392
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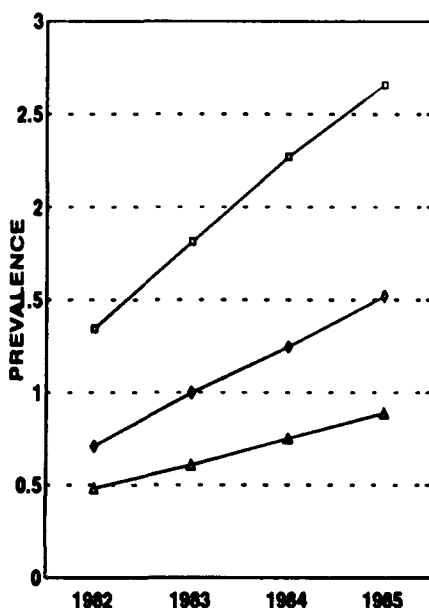
YEAR

Figure 3

The prevalence of IOL airmen in the total airman population by type and by year and the prevalence of IOL airmen in the aphakic airman population by year are presented in Figure 3. In the total airman population, the prevalence of IOL

airmen increased by 101.61% since 1982, while the prevalence of unilateral and bilateral IOL airmen increased by 72.12% and 199.23%, respectively. In the total aphakic airman population, the prevalence of IOL airmen increased by 53.18% since 1982.

**PREVALENCE OF I.O.L.
AIRMEN PER 1000 AIRMEN
BY CLASS AND YEAR**

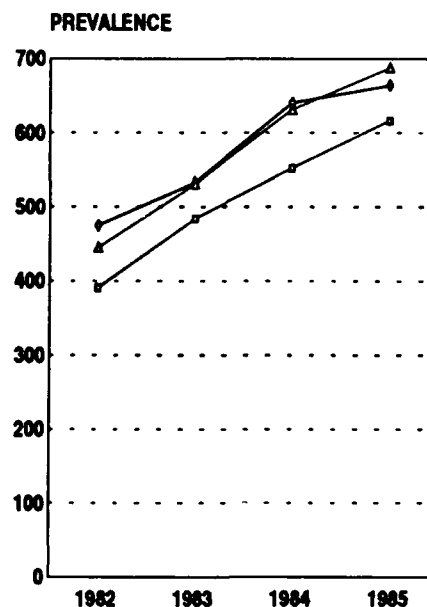


CLASS I	→	0.484	0.608	0.751	0.888
CLASS II	→	0.71	0.999	1.246	1.52
CLASS III	→	1.345	1.814	2.27	2.657

YEAR

I.O.L. = INTRAOCULAR LENS

**PREVALENCE OF I.O.L. AIRMEN
PER 1000 APHAKIC AIRMEN
BY CLASS AND YEAR**



CLASS I	→	445.455	530.973	631.148	687.943
CLASS II	→	474.934	533.04	640.351	663.984
CLASS III	→	391.07	483.986	552.315	616.387

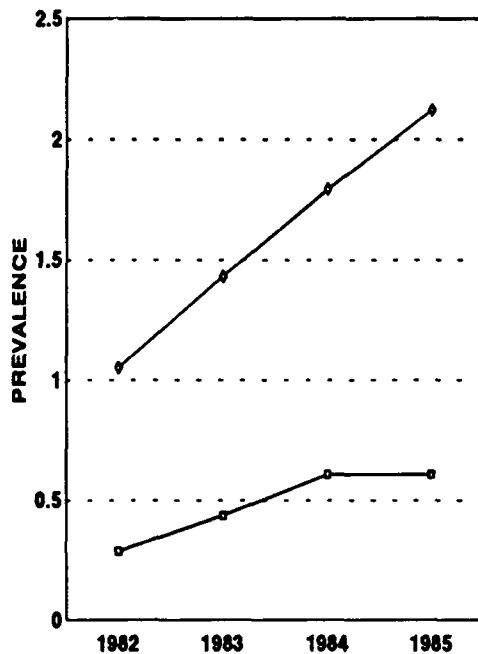
YEAR

Figure 4

The prevalence of IOL airmen in the total and aphakic airman populations by class of medical certificate and by year are presented in Figure 4. In the total airman population, the prevalence of second-class IOL airmen (114.12%) is higher than either first- (83.55%) or third-class (97.54%) since

1982. In the total aphakic airman population, the increases in prevalence of first- (54.44%) and third-class (57.62%) IOL airmen are approximately equal, and higher than second-class increases (39.81%) during the same period.

**PREVALENCE OF I.O.L.
AIRMEN PER 1000 AIRMEN
BY GENDER AND YEAR**

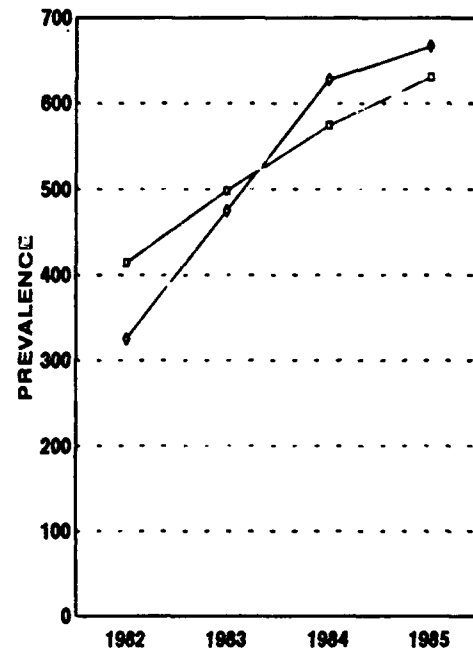


FEMALE	→	0.288	0.436	0.608	0.607
MALE	→	1.053	1.432	1.794	2.121

YEAR

I.O.L. = INTRAOCULAR LENS

**PREVALENCE OF I.O.L. AIRMEN
PER 1000 APHAKIC AIRMEN
BY GENDER AND YEAR**



FEMALE	→	325	475	627.907	666.667
MALE	→	414.188	498.447	574.337	630.769

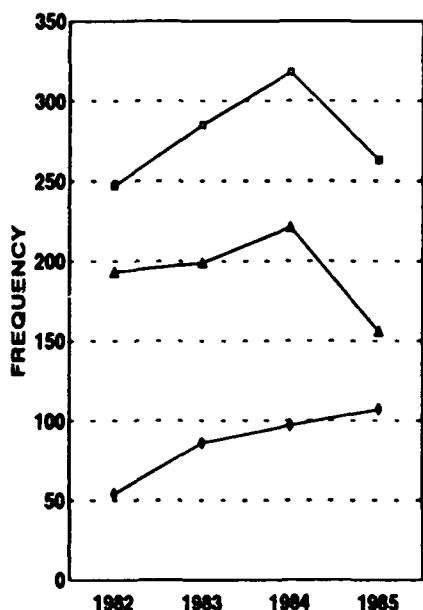
YEAR

Figure 5

The prevalence of IOL airmen in the total and aphakic airman populations by gender and by year are presented in Figure 5. In the total airman population, the increase in prevalence of female IOL airmen (110.82%) was slightly higher than

that of males (101.37%) since 1982. In the total aphakic airman population, the rise in prevalence of female IOL airmen (105.13%) was substantially greater than that of males (52.29%) over this period.

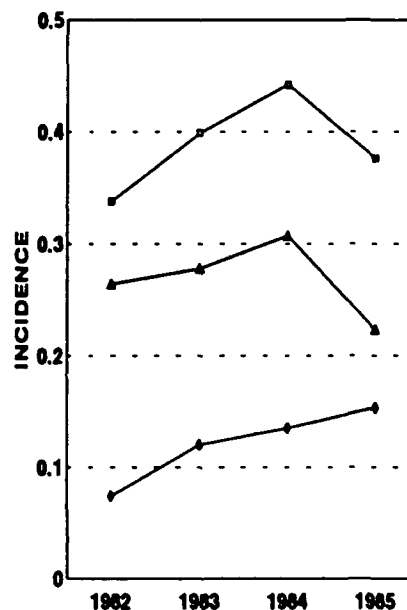
**NUMBER OF NEW CASES
OF I.O.L. AIRMEN
BY TYPE AND YEAR**



UNILATERAL	+	193	199	221	156
BILATERAL	+	54	88	97	107
TOTAL	+	247	285	318	263

YEAR

**INCIDENCE OF I.O.L.
AIRMEN PER 1000 AIRMEN
BY TYPE AND YEAR**



UNILATERAL	+	0.264	0.278	0.307	0.223
BILATERAL	+	0.074	0.12	0.135	0.153
TOTAL	+	0.338	0.399	0.442	0.376

YEAR

I.O.L. = INTRAOCULAR LENS

Figure 6

The number of new cases and incidence of IOL airmen per 1,000 airmen in the total airman population by type and by year are presented in Figure 6. In the last year of the study, there was a decline in the number of new cases of unilateral (-29.41%) and total (-17.30%) IOL implants. However, the number of new cases of bilateral IOL implants steadily increased 98.15% from 1982 to

1985. The incidence graphs follow a pattern very similar to that of the number of new IOL cases. In the last year of the study, the incidence of unilateral (-27.36%) and total (-14.93%) IOL implants declined. The incidence of bilateral IOL implants increased at a steady rate to 107.43% of the base level during the study period.

Using the Chi-Square statistic (X^2c), the number of older total and unilateral IOL airmen (≥ 50 years of age) was found to be significantly greater ($p < .001$), when compared to the number of younger IOL airmen (< 50 years of age) for both the total and aphakic airman populations for each year of the study. The average ratio of frequency¹ was 21.34 ± 2.24 for unilateral IOL and 29.28 ± 3.67 for bilateral IOL, when comparing airmen ≥ 50 years of age to those < 50 years of age for the total airmen population. During the same period, the average ratio of frequency for unilateral IOL in the total aphakic airman population was 2.14 ± 0.28 , and 1.18 ± 0.28 for bilateral IOL in the bilateral aphakic airman population. It is important to note that the ratio of frequency for all IOL airmen by type declined steadily over the four year study period. By 1985 the ratio of frequency for bilateral IOL airmen decreased to less than 1.00, indicating a higher ratio of bilateral IOL to bilateral aphakic airmen < 50 years of age, compared to the ratio of bilateral IOL to bilateral aphakic airmen ≥ 50 years of age.

DISCUSSION

IOL airmen have become increasingly prevalent in the civil airman population. As often used by the FAA in the evaluation of disease trends, the prevalence of IOL is defined as the number of IOL cases per 1,000 airmen in the total civil airman population. These statistics indicate that increases in the prevalence by type of IOL, class of medical certificate, and gender were greatest for bilateral, second-class certificate holders, and females. When the prevalence of IOL in the total aphakic airman population by total IOL, class of medical certifi-

cate, and gender were calculated, IOL use in aphakic airmen was found to have increased from approximately 41.2% in 1982 to 63.1% in 1985, a percentage increase of 53.18%. During the same period, the percentage increase in the prevalence by class of medical certificate was approximately equal for first- and third-class, but was substantially lower in second-class IOL airmen. The percentage increase in the prevalence by gender was approximately twice as high for female IOL airmen as their male counterparts.

The difference in IOL prevalence statistics, when comparing prevalence in the total and aphakic airman populations, is substantial. For example, when analyzed in the total airman population by gender, the prevalence of female IOL airmen is approximately one-third of male IOL airmen, which appears to contradict previous prevalence studies that have indicated more women require cataract surgery than men (14,15), although this may be related to the difference in the gender age distributions in the airman population. However, when analyzed in the aphakic airman population, the prevalence of female and male IOL airmen is approximately equal, and females actually have greater acceptance of IOL than their male counterparts in the later years of the study period. This suggests that, when aphakic and flying, females prefer to be corrected with an IOL, rather than alternative therapeutic modalities. Furthermore, prevalence of IOL by class of medical certificate held in the total airman population indicates a larger percentage increase in second-class airmen, while the prevalence of IOL in the aphakic airman population reveals a substantially larger percentage increase in first- and third-class airmen. To identify the use of IOL in the airman population in future studies, less error may be induced by also calculating prevalence in the aphakic airman population.

¹ Ratio of Frequency = $\frac{A/B}{C/D} = A/B \times D/C$

A = IOL population ≥ 50

B = IOL population < 50

C = Non-IOL population ≥ 50

D = Non-IOL population < 50

The decline during the final study year in the number of new cases and incidence per 1,000 airmen of unilateral and total IOL airmen is puzzling, in light of the known increasing frequencies of cataract surgery and IOL implantation in the United States during the study period. The number of new cases and the incidence per 1,000 airmen

statistics may be important indicators of the acceptance of IOL by airmen and functional applicability of new corrective devices for performing flight-related activities. The reasons for the decline in incidence is speculative, and further research to evaluate this and other trends of IOL use in the airman population in subsequent years is planned.

The statistically significant difference between the use of IOL in the older age categories (≥ 50 years of age) for both the total and aphakic airman populations was expected, since cataract is an age associated disorder. However, the declining ratio of frequency of IOL between the age categories (≥ 50 and < 50 years of age) during the study period suggests that IOL use is no longer strictly an age associated condition, and an increasing number of younger aphakics may be expected to have an IOL implanted (Note: While intraocular lens implants were recommended only for the elderly and only in 1 eye during the mid-to late-70s, these surgical restrictions were rescinded in the 1980s (16).). It was most surprising that the ratio of frequency of IOL declined in the aphakic airman population to the point that those airmen having bilateral aphakia actually have a higher comparable number of IOL in both eyes in the younger age category than in the older age category in the last year of the study. These younger IOL airmen should be on flight status for substantially longer periods than the FAA has previously experienced.

Considering these findings, the use of IOL by airmen may have several future aeromedical certification implications to the FAA, which include:

- 1) Although the improvements in surgical techniques, IOL fabrication, IOL design, and modern sterilization techniques have reduced the incidence of complications of cataract surgery with intraocular lens implantation in recent years (1), the use of different styles and applications of IOL has been associated with ocular problems, which include: higher incidence of opacified posterior capsule (17); color vision shifts (18,19,20); decreased contrast sensitivity (21); reduced visual field (22,23); glare and light reflections under scotopic

conditions (20); increased cystoid macular edema, uveitis, glaucoma, hyphema, iris trauma (24); visual problems associated with fixed focal lengths (25), pupillary block (26), and endophthalmitis (27).

- 2) Evolving IOL applications and materials, such as bifocal/multifocal lens (28), soft and/or foldable lens (28), telescopic intraocular lens (29), monovision correction (30), ultraviolet absorbers (31), and polycarbonate plastic (32) materials, may result in future certification policy considerations for the FAA as certain lens types may be less acceptable for correcting aphakic pilots than others. These new devices will need to be continually monitored to assess their effects on vision in an aviation environment.
- 3) The effects of aviation stressors on vision with an IOL in the eye, especially when surgical complications are present (e.g., acceleration or vibration may displace the IOL, glare may impair the visual performance of the IOL), and the long-term effects on vision and health of the eye (leaching of unreactive monomers and various additives from IOL material (33)) have not been fully investigated. (Note: Future research to evaluate the vision performance of IOL users under different aviation-related stressors is planned by our laboratory.)
- 4) An increased number of younger (< 50 years of age) IOL airmen, especially with bilateral IOL implants, in the total airman population suggests that the FAA will have these visually "impaired" airmen throughout much of their aviation careers and for much longer periods than previous aphakic pilots (Note: Aphakia - with or without IOL correction - is considered a visual impairment weighted by the American Medical Association with a 50% decrease in value of the remaining corrected central vision for unilateral conditions; while with bilateral conditions, the corrected central vision decreases an additional 25% (34).).
- 5) The increased use of IOL in first-class aphakic airmen, who are frequently in the more demanding visual performance environment of the air transport pilot, suggests that the ergonomic design of future cockpits may need to be

modified to accommodate the visual limitations of an IOL.

- 6) The lower prevalence of female IOL airmen in the total airman population suggests that women may be self-selecting themselves from active flying status at a higher rate than their male counterparts. Conceivable reasons for voluntary removal from active flying status include: a perceived or actual sensory (visual) loss may be considered to be compromising while flying; submitting for a waiver may be deferred due to economic considerations; other physiologic impairments may be considered a safety hazard; and, since the majority of females are not pilots by profession, the financial necessity to continue flying is not a factor.
- 7) With the large number of intraocular lenses (over 100 lenses in 1987 (35)) available on the commercial market and with new designs and applications being developed, any endorsement of IOL implantation for pilots should include recommendations that the lenses used be approved by the Food and Drug Administration, that an adequate post-operative healing period has elapsed, and the resulting refractive error and visual acuity have stabilized within medical standard guidelines.

Although an increasing number of aphakic airmen use IOL implants, it is important to note that a substantial number continue to use contact lenses to correct for aphakia. Of all types of contact lenses, aphakic extended wear contact lenses, while representing an important therapeutic alternative, carry the greatest risk of associated infections (36). Therefore, aphakic airmen with extended wear contact lenses need to be particularly well informed about the risks of such lens use.

CONCLUSIONS AND RECOMMENDATIONS

In this study, artificial lens implant use in the civil airman population is described. Major findings include:

- 1) The prevalence of IOL airmen has increased in the total airman population, and, with the

numerous IOL applications and materials being developed, there is a need to continue evaluating their impact on flight performance and aeromedical certification. (Note: Although not reported in this manuscript due to the inconsistent information in the airman medical records, IOL airmen included all major types of artificial lens implants [anterior chamber, iris-fixated, and posterior chamber], and it was not unusual to find aphakic airmen with different types of IOL implants between 2 eyes. The impact on visual performance in flight simulations of these various types of lens implants is being considered for further evaluation using improved medical examination techniques in future research protocols.)

- 2) Using the total airman population to evaluate prevalence of IOL use, such as by class of medical certificate held and gender, can give misleading and incomplete information. It is recommended that the aphakic airman population, as well as the total airman population, be used to evaluate future prevalence statistics for such devices, so more valid information can be obtained.
- 3) The incidence of IOL per 1,000 airmen declined in the last year of the study period. The incidence statistic may provide valuable information on the acceptance of new therapeutic devices by airmen in their flight activities and should be included in evaluating the use of these and other ophthalmic devices in the future.
- 4) The prevalence of IOL airmen <50 years of age is increasing, reinforcing the fact that the use of IOL implants is less of an age-associated phenomena. These younger IOL airmen will be active in the pilot population for longer periods of time than the FAA has previously experienced. Continued monitoring of these airmen is recommended to determine long-term effects of IOL implantation on ocular health and safety.

Current FAA vision standards and the additional waiver process appear to be sufficient safeguards for the aeromedical certification of aphakic and IOL applicants. To aid in the aeromedical certification and clinical review of the long-term

occupational health hazards and compatibility with safe flight operations of evolving IOL devices, it is suggested that the Aviation Medical Examiner ensure that certain information, including date(s) and type(s) of intraocular lens implantation(s), complications, secondary procedures, use of investigative devices, etc., be documented on each aphakic airman's medical record. Continuing to evaluate prior administrative medical actions and to monitor emergent therapeutic modalities, will support the FAA's policy to ensure the safety of the civil aviation community and the flying public.

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